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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,887	09/29/2006	Kei Fujinaga	KUZ0035US.NP	1279
26259 7590 04/03/2009 LICATA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053				
EXAMINER				
LI QIAN JANICE				
ART UNIT		PAPER NUMBER		
1633				
NOTIFICATION DATE		DELIVERY MODE		
04/03/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary**Application No.**

10/594,887

Applicant(s)

FUJINAGA ET AL.

Examiner

Q. JANICE LI

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 10, 11 and 31-48 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 7, 10, 11 and 31-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

The preliminary amendment file 9/26/06 is acknowledged. Claims 7, 10, 11, 31-48 are pending and subject to a restriction requirement.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

- I. Claims 7, 31-34 are drawn to a nucleic acid encoding an anti-prion antibody, wherein the heavy chain-coding sequence is selected from the group consisting of SEQ ID Nos: 1, 3, 5, 30, 32, 34, and the light chain-coding sequence is selected from the group consisting of SEQ ID Nos: 2, 4, 6, 31, 33, and 35; the nucleic acid may also be a degenerate code, a variant or complement of the aforementioned sequences, and host cells transformed with the nucleic acid. Classified in class 536, subclass 23.1, and class 435, subclass 320.1, 325, and 455.
- II. Claims 10, 11 are drawn to an anti-prion antibody encoded by a nucleic acid, wherein the heavy chain-coding sequence is selected from the group consisting of SEQ ID Nos: 1, 3, 5, 30, 32, 34, and the light chain-coding sequence is selected from the group consisting of SEQ ID Nos: 2, 4, 6, 31, 33, and 35; the nucleic acid may also be a degenerate code, a variant or complement of the aforementioned sequences. Classified in class 530, subclass 387.1.

- III. Claims 36, 40 are drawn to a method of treating Prion diseases using mesenchymal cell not genetically modified for secreting antibody of group II. Classified in class 424, subclass 93.1.
- II. Claims 37, 38, 40, 46-48 are drawn to a method of treating Prion diseases using an antibody-secreting cell, wherein the cell may be a mesenchymal cell. Classified in class 424, subclass 93.21.
- III. Claim 41 is drawn to a method of treating Prion diseases using a recombinant vector. Classified in class 514, subclass 44.
- IV. Claims 42-45 are drawn to a method of treating Prion diseases using an anti-Prion antibody. Classified in class 424, subclass 130.1.
- V. Claim 48 is directed to a method for delivering a substance to a lesion site of a prion disease using mesenchymal cells. Classification is to be determined depending on the nature of the substance.

Note each of groups I and II listed above comprises multiple inventions each defined by an antibody with a specific combination of H- and L-chain coding sequence. Upon election of groups I or II, further identification of a specific combination of heavy and light chain sequences of the antibody is required, e.g. an antibody comprising SEQ ID Nos: 1 and 31. This is an election of an invention, not a species election, since each invention is directed to a structural distinct antibody or nucleic acid encoding such.

Claims 35, 39 link inventions III through V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions

shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions IV, V and I are related as product and process of use. Inventions VI and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the subject may be treated with materially different substances such as indicated in groups III-VI, and the product as claimed may be used in a materially different process such as producing an antibody.

Further, a search for the invention of the groups would not be coextensive because a search indicating the process is novel or unobvious would not extend to a holding that the product itself is novel or unobvious; similarly, a search indicating that

the product is known or would have been obvious would not extend to a holding that the process is known or would have been obvious. Further, the inventions raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. Therefore, restriction for examination purposes as indicated is proper.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, a serious burden is imposed on the Office to perform a complete search of the defined areas in both the patent and non-patent literature if all the groups are examined together. Therefore, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

- Invention groups IV-VI are directed to a method using materially different nucleic acid molecules, antibodies, and cells. If one of the inventions III-V is elected, further election of a species is necessary, wherein the species is defined by a specific structure of the antibody. For example, an antibody comprising a heavy chain encoded by SEQ ID No: 1 and a light chain encoded by SEQ ID No: 2.
- Upon election of group I, III, IV, VII further elect a specific type of mesenchymal or antibody secreting cell, such as a bone marrow cell.
- Upon election of group VII, further election of a specific substance to be delivered.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is

allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is **571-272-0730**. The examiner can normally be reached on 9:30 am - 7:30 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Weitach** can be reached on **571-272-0739**. The **fax** numbers for the organization where this application or proceeding is assigned are **571-273-8300**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

For all other customer support, please call the USPTO Call Center (UCC) at **800-786-9199**.

*/Q. JANICE LI/
Primary Examiner, Art Unit 1633*

Q. Janice Li, M.D.
Primary Examiner
Art Unit 1633

QL

April 1, 2009

